

The Food Safety Modernization Act and Michigan Food and Feed Laws



Summary of Need

Market driven food safety requirements are increasing for food and feed companies due the Food Safety Modernization Act (FSMA).

The new federal rules have resulted in:

- Additional market requirements related to food and feed safety.
- Major differences between federal and Michigan regulations.
 - This will increase federal regulatory presence in Michigan, as an inspection performed by MDARD will no longer meet the needs of an FDA inspection. Market driven requirements are gravitating toward the new FSMA rules.
 - Inability of food companies to meet the new requirements will reduce market access for growers and processors.

Adoption of the new rules will allow MDARD to better assist industry in meeting those standards and prevent duplication of effort between federal and state regulators.

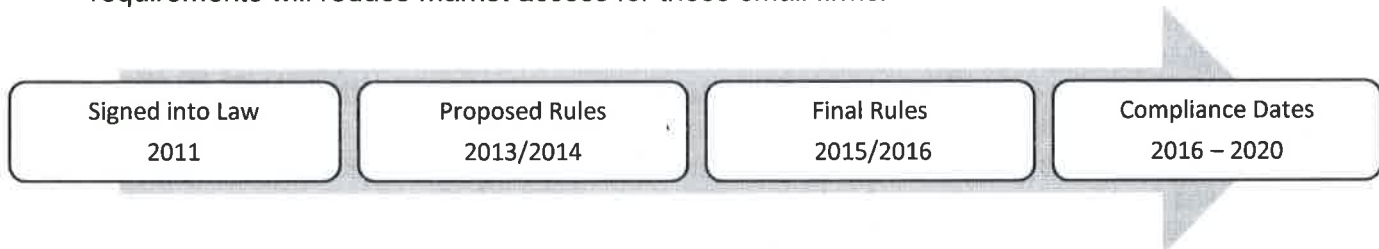
- The food and agriculture industry is one of the Big Three industries in our state, contributing \$101.2 billion annually.
- Food safety is critical to continued growth of the state's agriculture industry.

Summary of Proposal

- Assure market access for Michigan agriculture by updating Michigan food and feed laws to maintain national and global consistency. This includes adopting the federal Food Safety Modernization Act (FSMA) and associated rules that have recently been finalized.
- Fix an accidental food service fee reduction that occurred during passage of SB774 of 2016 - Vending Bill. The fix does not increase any fees. Fees are currently lowered for FY2017 and would move back to original amounts in FY2018.

Why Now?

- Food Companies are experiencing increased pressure to meet the new requirements due to implementation of FSMA. Large companies were required to comply with the new rules on 9/17/16. Small and very small firms, which need the most assistance with the new standards, will be required to comply within one to four years depending on size and type of business. Inability to meet the new requirements will reduce market access for these small firms.



Action Needed

To maintain market access for Michigan agriculture it is necessary to re-adopt an existing section of the Michigan Food Law. FSMA and current food growing, processing and transportation standards have been added to these sections since the last adoption in 2012.

What the Food Safety Standards Cover



Growing and Harvesting of Produce

- Produce that is typically eaten raw



Manufacture, Pack and Hold of Food

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Intentional Contamination



Transportation

- Sanitary Transportation of Food by Motor or Rail



Importation

- Foreign Supplier Verification Program
- Accreditation of Third-Party Certification Bodies

Results of No Action

- MDARD stays with current FDA PROCESSING STANDARDS, which will get increasingly outdated and be of limited value to industry and outside customers.
 - Michigan hasn't written its own food safety standards in over 20 years. If FSMA is not adopted, it is unknown how Michigan will update food processing laws to stay current.
- FDA presence in Michigan will increase.
 - Firms that now receive one inspection that meets both State and Federal requirements, will now receive two inspections, one from MDARD and one from the FDA. The two inspections will evaluate businesses using different regulatory requirements.
 - FDA will conduct produce safety inspections on farms.
- Export certificates issued by MDARD will become meaningless to other countries.
- MDARD inspectors will not be using current standards, will not be trained to them and will not be able to assist customers with FSMA compliance questions.
- Nationally available training courses won't be aligned with Michigan standards.
- Opportunities for Michigan to do contract inspection work, and the federal funds that come with these contracts, will be eliminated. This will significantly reduce state food safety inspection staff and their level of training. Currently, Michigan has approximately \$750,000 annual contract and a training grant with FDA that supports five MDARD inspection staff and trains all 58 staff.
- Eliminates Michigan's ability to meet FDA Voluntary Manufacturing Standards. MDARD is currently in almost full compliance with these standards, but compliance is based on adoption of the recommended federal laws.



Food Safety Modernization Act and Michigan Food Laws

Michigan Department of Agriculture and Rural Development
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Jim Bowes, Acting Division Director
Food and Dairy Division
Michigan Department of Agriculture and Rural Development

p. 517-284-5671
bowesj@michigan.gov

Summary of Proposal

- Adopt federal food safety rules to:
 - Remove the regulatory burden created by a patchwork of food safety requirements for Michigan's food processors;
 - Maintain market access for processed products from Michigan; and,
 - Maintain market access for Michigan's fruit and vegetable farmers.
- Fix a technical error created with the passage of SB 774 in June, 2016. The fix resets the food service fee -- which was not the subject of the bill -- to its 2016 level.

Objectives

- Assure market access for Michigan food processors, farmers and others in the supply chain by aligning state law with national standards.
- Provide industry with consistency and stability they need to operate in interstate markets.
- Ensure certificates of free sale remain acceptable in global market place.
- MDARD processor inspections will align with federal standards and be accepted for supply chain management purposes. This will reduce the need for additional third party audits.
- Ensure MDARD is conducting regular food safety inspections instead of the federal Food and Drug Administration.
- Ensure MDARD is the lead agency for routine on farm produce inspections with an "educate before you regulate" approach rather than the federal Food and Drug Administration.

Action Needed

To achieve the objectives set out above, it is necessary to re-adopt the following existing section of the Michigan Food Law. FSMA and current food growing, processing and transportation standards have been added to these sections since our last adoption in 2012.

289.7112 Adoption of federal regulations.

Sec. 7112.

(1) 21 CFR parts 1, 70, 73, 74, 81, 82, and 100 to 199, as set forth on the effective date of the amendatory act that added this section, are adopted by reference, except to the extent that provisions of this act and rules promulgated under this act specify different requirements.

(2) The director, by promulgation of a rule, may adopt any changes or updates to 21 CFR parts 1, 70, 73, 74, 81, 82, and 100 to 199.

History: Add. 2012, Act 178, Eff. Oct. 1, 2012

Results of No Action

- **FDA presence in Michigan will increase.**
 - Firms that now receive one inspection that meets both state and federal requirements will now receive two inspections -- one from MDARD and one from the FDA. The two inspections will evaluate businesses using different regulatory requirements.
 - FDA will conduct produce safety inspections on farms.
 - Michigan food companies will be subjected to federal inspection since MDARD will not be qualified to do contract inspection work for FDA. This will reduce state food safety inspection staff and their level of training. Currently, Michigan has an approximately a \$750,000 annual contract and a training grant with FDA supporting five MDARD inspection staff and training for all 58 staff.
- Export certificates issued by MDARD will become meaningless to other countries making it difficult for Michigan companies to sell processed products outside the United States.
- Customer service capabilities will decline since MDARD inspectors will not be able to assist customers with FSMA compliance questions because they will not be using nor be trained to current standards.
- MDARD costs will increase since nationally available training courses won't be aligned with Michigan standards requiring Michigan to create and support its own training system.
- Eliminates Michigan's ability to meet FDA Voluntary Manufacturing Standards which increases food safety for Michigan citizens. MDARD is currently in almost full compliance with these standards but compliance is based on adoption of the recommended federal laws.
- MDARD stays with current FDA PROCESSING STANDARDS, which will get increasingly outdated and be of limited value to industry and outside customers.
- Michigan hasn't written its own food safety standards in over 20 years. If FSMA is not adopted, it is unknown how Michigan will update food processing laws to stay current.

Summary of Need

Market driven food safety requirements are increasing for food processors and produce growers. A large reason for this change is the Food Safety Modernization Act.

The new federal rules have resulted in:

- Additional market requirements for food companies. Since the rules represent minimum regulatory standards, many companies are using them as the minimum requirements for ALL purchasing to prevent the liability and brand damage.
- Major differences between federal and Michigan regulations. This can cause confusion with the industry as companies will be required to meet two separate regulatory standards unless Michigan adopts the federal standard.
 - It will also increase federal regulatory presence in Michigan, as an inspection performed by MDARD will no longer meet the needs of an FDA inspection.
 - Market driven requirements are gravitating toward the new FSMA rules.

- Inability of food companies to meet the new requirements will reduce market access for growers and processors.
- Adoption of the new rules will allow MDARD to better assist industry in meeting those standards and prevent duplication of effort between federal and state regulators.

Example of Need

- The FSMA Produce Safety Rule is intended to reduce the risk of product contamination during the growing and harvesting steps.
- According to the Center for Disease Control (CDC) food safety statistics of 48 million illnesses per year, 128,000 hospitalizations and 3,000 deaths are due to foodborne diseases.
- Produce that is consumed raw does not receive a processing step (like cooking) to reduce hazards that were present while the product was being grown. For example, contaminated irrigation water can contaminate the produce it gets sprayed on. When that produce is harvested, it makes it to the store shelf or a restaurant plate without any processing to address the contamination.

Impact of Food Safety Incidents at Michigan Processors

	Incident 1	Incident 2	Incident 3	Incident 4
Food Category	Apple Sauce	Animal Feed	Frozen Fruit	Soy Flour and Grits
Employees Out of Work	200	-	50	20
Amount of Downtime	9 weeks	8 weeks	12 Weeks	Permanent
Impact to Company	\$60 Million in product loss. \$5 Million in Capital Improvements	Over \$5 million in animal and product loss. 55,000 turkey deaths; limited movement of 35,000 swine to market; 500 tons feed	\$7 - \$8 Million in product loss, Facility improvements and lost wages	Closed
Where	Northern Michigan	West Michigan	Southwest Michigan	East Michigan
When	2016	2014	2012	2010 – 2012
Contaminant	mold and filth	Lascadoil	Listeria M	Salmonella

Food safety inspectors providing skilled evaluation of food growing and processing establishments using current, science-based, national requirements is critical to main food safety and market access, and maintain Michigan's reputation for safe food.

One example of contamination happened in Michigan in 2014. Cantaloupe grown on a farm in Stanwood was found to be contaminated with Salmonella. MDARD performed an investigation of the farm that grew the fruit and found several issues which most likely contributed to the contamination.



Animals near the packing area.



Multi-use hay covered cart used for harvested produce.

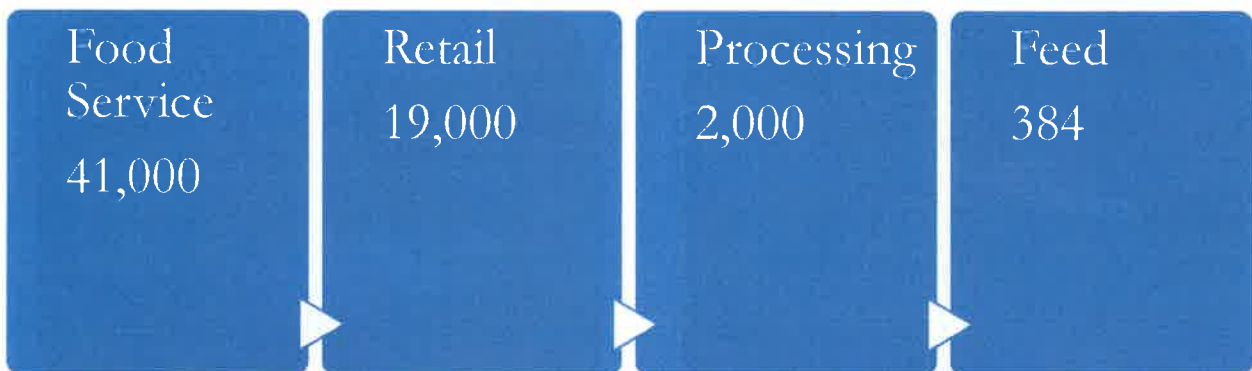


Deer intrusion in the growing field.



Irrigation pond directly next to and down hill from a cow pasture.

Scope of FSMA Rule Adoption



Buyer requirements and export requirements of other countries are likely to affect many of these businesses are not directly regulated by FSMA rules.

Since the rules represent minimum regulatory standards, many companies are using them as the minimum requirements for purchasing to prevent the liability and brand damage of being involved with an incident like the one described above.

Other Examples of Need:

Exporting

Many firms receive *Certificates of Free Sale* from MDARD in order to sell product outside the U.S. Since FSMA is required for both foreign and domestic firms, other countries have stated they will impose the same standards on products coming out of the U.S. as the U.S. requires for imports under FSMA. This means MDARD's *Certificate of Free Sale* will no longer help firms export products if Michigan's law is not aligned with FSMA.

Reduce Inspection/Audit Fatigue

Under FSMA, manufacturers are required to have a supply chain management program. In many cases, this will require on-site audits of suppliers. This requirement will increase the need for third party audits. However, a government inspection can meet the requirement of an on-site audit if the inspection is aligned with FSMA requirements. Therefore, if MDARD inspections are aligned with the FSMA requirements, the need for some firms to get a third party audit will be reduced. This will be especially helpful for small firms that want to supply larger companies.

Processor and Large Grower Assistance

Firms frequently ask MDARD staff for assistance with meeting and understanding the FSMA requirements. A study was conducted through the Association of Food and Drug Officials in 2012 to gauge industry's knowledge of the law and determine where industry will go for assistance. The results showed that the majority of firms in Michigan will look to MDARD for help with FSMA. Adopting the rule will allow MDARD staff to meet the needs of industry seeking guidance to comply with FSMA.

Small Produce Grower Assistance

Even firms exempt from the new federal regulations are experiencing additional market driven standards. For example, potato growers are exempt from the Produce Safety Rule but buyers such as Frito Lay have increased their requirements, including a requirement for third party audits that show compliance with the rule. **Assisting small growers was a 2013 Governor's Food Policy Council recommendation.**

Benefits to Industry

Being licensed by MDARD means a food business is meeting state food safety requirements. This is monitored and verified through MDARD's Food Safety and Inspection Program. If MDARD is not aligned with and inspecting against standards equal to federal requirements, the state license loses value in the marketplace.



Why are there new FSMA Food Safety Standards?

Developed as an industry/government partnership.

- Federal food safety standards were outdated.
- Industry was requiring a patchwork of private food safety audits.
- Everyone was reacting to numerous, large, national outbreaks instead of focusing on prevention.
- Fresh produce was emerging as the leading cause of foodborne illness outbreaks.
- There were no on-farm food safety produce standards.
- Imports were an increasing source of contaminated food.
- Transportation was being increasingly recognized as needing some basic food safety standards. MDARD in conjunction with the Michigan State Police was the first state to demonstrate the problems with temperature abuse and cross-contamination during transport.

Food Safety Standards Directly Covered by FSMA



Growing and Harvesting of Produce

- Produce that is typically eaten raw



Manufacture, Pack and Hold of Food

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Transportation

- Sanitary Transportation of Food by Motor or Rail

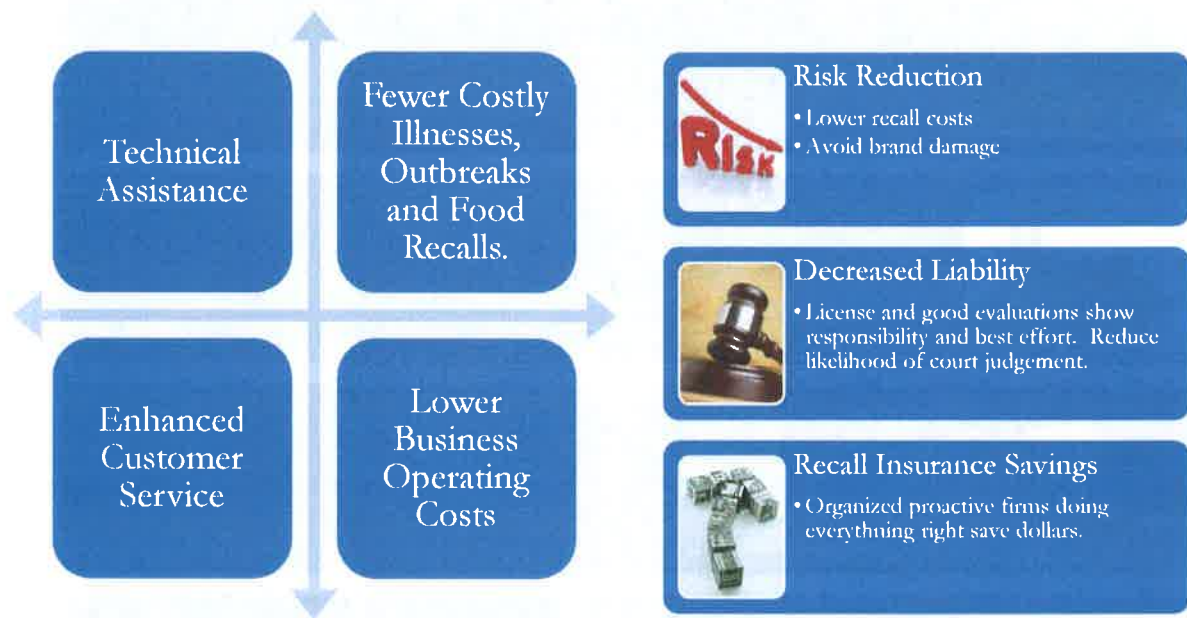


Importation

- Foreign Supplier Verification Program
- Accreditation of Third-Party Certification Bodies

- The new FSMA rules cover growing and harvesting practices for produce that is typically eaten raw. There are exemptions for small farms, produce destined for commercial processing and produce that is not typically eaten raw.
- There are additional requirements for firms that manufacture, pack and hold human food or animal feed. These firms are covered by current regulations. However, new requirements have been added that include the need for a Food Safety Plan and also a strategy to address intentional adulteration.
- Sanitary transportation practices have also been created to address the shipping of food. Previously, only general sanitary practices applied to these operations. The new rule creates more specific requirements for that industry.
- Lastly, as a means of leveling the playing field between domestic and imported products, a new requirement has been created for importers of food. The importer of record is required to ensure the foreign suppliers of each product imported are compliant with the FSMA rules.

How Using Current Food Safety Laws Help Businesses

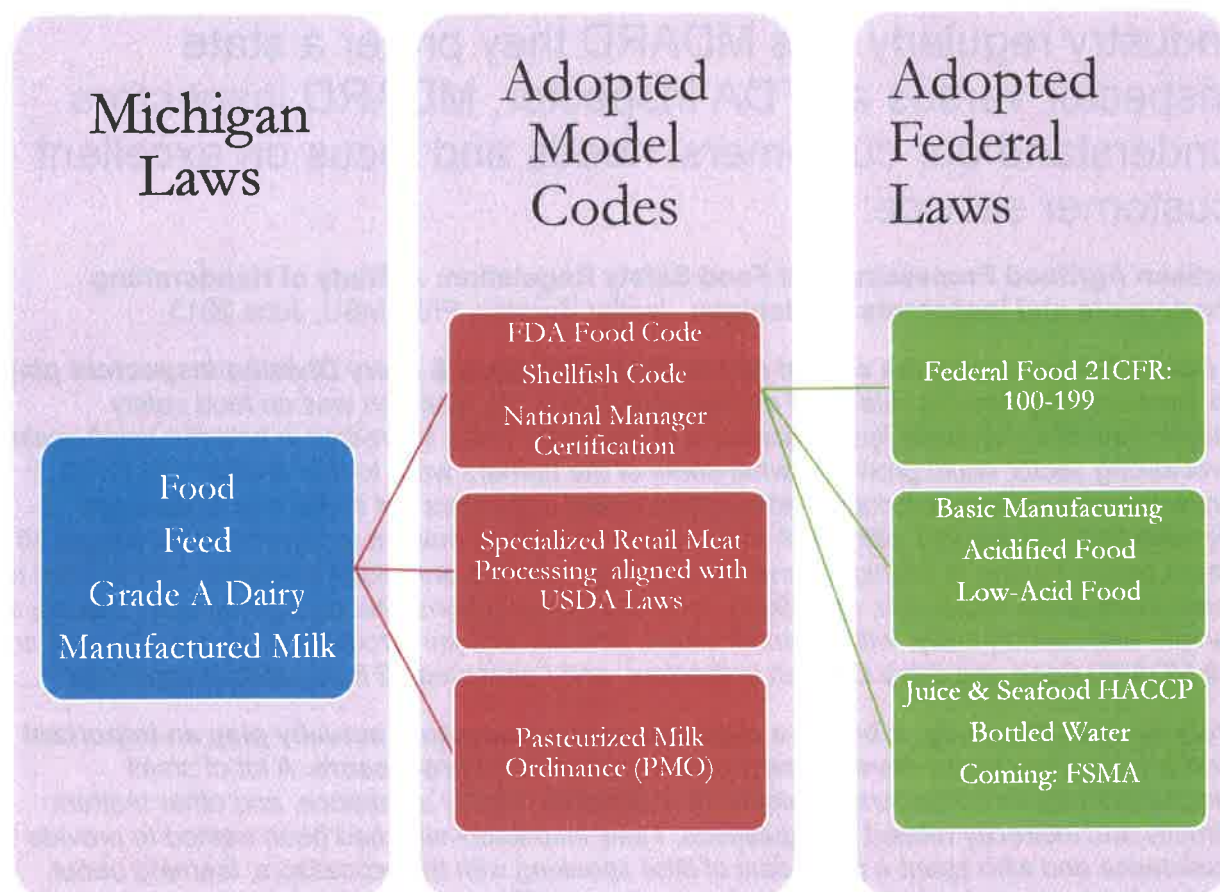


Food Product Recalls Can be Extremely Costly

According to industry publication, *Food Production Daily*:

"In the U.S. alone, according to a New Jersey PIRG study, food recalls and foodborne illnesses bear an annual price tag of approximately \$77 billion (including discarded product, revenue, healthcare costs, lost wages and litigation and other expenditures). The damage to a company's reputation, while harder to measure, can be even more devastating."

Food recalls cost billions each year, By Jenni Spinner+, 11-Sep-2013,
<http://www.foodproductiondaily.com/Safety-Regulation/Food-recalls-cost-billions-each-year>



Alignment allows consistent standards, education and processes world-wide based on best science and technology.

State Laws Align with Federal Laws and Model Codes

- Pasteurized Milk Ordinance
- Model Food Code
- Model Shellfish Code
- Food Safety Modernization Act
- Code of Federal Regulations

Align with International Laws and Standards

- CODEX (global use)
- Safe Food for Canadians Act
- Mexican Food Safety Laws

Align with Voluntary Industry Standards

- SQF, Global GAP, BRC, PrimusGFS

Industry regularly tells MDARD they prefer a state inspector versus an FDA inspector. MDARD inspectors understand our customers' needs and focus on excellent customer service:

Artisan Agrifood Processing and Food Safety Regulation: A Study of Handcrafting Processors and Inspectors in Michigan. Jenifer Buckley, PhD, MSU, June 2013

I would like to convey the critical role that MDARD Food & Dairy Division inspectors play in encouraging small-scale food entrepreneurship. My research was on food safety inspections of small-scale food processors in Michigan. I was interested in how the small-scale processing sector could grow and what some of the barriers were to that growth. Of course, I knew the conventional wisdom, that regulations and inspectors get in the way of business development- I'd worked with small-scale farmers and food makers in Minnesota for almost 15 years before I came to Michigan, and I was familiar with the anecdotal evidence. So I wanted to learn more about regulation, specifically food safety inspections. During my research, I spoke at length, and confidentially, with 27 small bread, cheese, and jam processors across the state and 19 MDARD Food and Dairy Division inspectors, and I observed 12 food safety inspections.

Very early in the study, it became clear that many inspectors actually play an important and positive business development role for small food processors. A lot of small processors rely on inspectors for technical assistance, quality assurance, and other matters directly and indirectly related to regulations. I saw inspectors who had been trained to provide assistance and who spent a great deal of time speaking with the processors, learning about their operations, and explaining the rationales for specific requirements.

In my private conversations with them, small food processors credited their inspectors with helping them make sound operational decisions to improve food safety and product quality. (Even processors who did not want the government "in their business" told me that they had come to respect and trust their inspectors.) Processors valued inspectors as "a fresh set of eyes" who noticed risks that they might have otherwise missed. For example, one baker told me about an episode in which his inspector required him to replace the bakery's ceiling lights with shatter resistant bulbs by a certain date. And he told me just how expensive the new bulbs were. Yet, he said, "That was the best thing ever...I think it was three months later that I hit a light bulb [with a long handle], and it didn't shatter in a million pieces and go into all our dough and all our product. It stayed contained."

Business Growth

To: Quaine, Erin (MDA)
Subject: BIG Thank You!
From: Deborah Kidder
Sent: Friday, January 16, 2015 12:50 PM

Hello, Thank you for your time and all your wonderful help with our project. We appreciate your helpfulness and knowledge. Erin, please forward this email on to Barb.

Barb, what a treat to meet you; it is always so obvious when you meet a follow animal lover! You and Erin put in a long day; thank you for all your time and expertise. Erin has been very informative and helpful; we find it very easy to work with her. If you are ever in the area stop by; I would love to share with you our "big" vision and show you around (perhaps when things are green again :-)
Top of the Day, Debi

Food Recall

Sent: Friday, November 21, 2014 8:14 AM
To: Settimo, Ken (MDA)
Cc: Cindy Baswell; Don Swanson
Subject: Many Thanks.....

Ken....

I would be remiss if I didn't take the opportunity to Thank-You for your guidance, education, and support during our recent recall. Your knowledge and ability to clarify in lay terms for us resulted in a smooth transition with minimal disruption to our campus. Please extend our thanks to all from who were involved. Looking forward to our continuing partnership with you and your team.

*Marta M. Mittermaier
Manager, RHS Support Services
Associate Director, Culinary Services
Michigan State University*

